

LISTING OF CLAIMS

1. (Currently amended) A composition for the enhanced delivery of a local anesthetic agent through a body surface, comprising a formulation of:
 - (a) a therapeutically effective amount of the local anesthetic agent;
 - (b) a pharmaceutically acceptable inorganic base in an amount effective to provide a pH within the range of about 8.0-13.0 at the body surface during administration of the local anesthetic agent and to enhance the flux of the local anesthetic agent through the body surface without causing damage thereto; and
 - (c) a pharmaceutically acceptable carrier suitable for topical or transdermal drug administration, the inorganic base comprising an inorganic hydroxide present in an amount of about 0.75 to 2.0% of a topically applied formulation or a drug reservoir of a drug delivery system or patch.
2. (Original) The composition of claim 1 wherein the basic permeation enhancer is contained within an aqueous formulation.
3. (Original) The composition of claim 2 wherein the aqueous formulation has a pH within the range of about 8.0-13.0.
4. (Original) The composition of claim 3 wherein the pH is within the range of about 8.0-11.5.
5. (Original) The composition of claim 4 wherein the pH is within the range of about 8.5-10.5.
6. (Original) The composition of claim 2 wherein the aqueous formulation is selected from the group consisting of a cream, a gel, a lotion, and a paste.

7. (Original) The composition of claim 1 wherein the composition provides for at least about 1.5-fold enhanced delivery.

8. (Original) The composition of claim 7 wherein the composition provides for at least about 3-fold enhanced delivery.

9. (Original) The composition of claim 1 wherein the local anesthetic agent is an acidic species.

10. (Original) The composition of claim 9 wherein the base is present in an amount that is the total of

- (a) the amount required to neutralize the acidic species plus
- (b) an amount equal to about 0.5-4.0 wt % of the composition.

11. (Original) The composition of claim 1 wherein the local anesthetic agent is a non-acidic species.

12. (Original) The composition of claim 11 wherein the base is present in an amount equal to about 0.5-4.0 wt % of the composition.

13-16. (Canceled)

17. (Original) The composition of claim 1 wherein the base is effective to provide a pH within the range of about 8.0-11.5 at the localized region of the body surface during administration of the local anesthetic agent.

18. (Original) The composition of claim 17 wherein the base is effective to provide a pH within the range of about 8.5-10.5 at the localized region of the body surface during administration of the local anesthetic agent.

19. (Original) The composition of claim 1 wherein the local anesthetic agent is selected from the group consisting of benzocaine, benzyl benzoate, bupivacaine, calamine, chloroprocaine, chloroxylenol, cinchocaine, cocaine, dexivacaine, diamocaine, dibucaine, dyclonine, etidocaine, hexylcaine, ketamine, levobupivacaine, lidocaine, menthol, mepivacaine, oxethazaine, phenol, pramoxine, prilocaine, procaine, proparacaine, propoxycaine, pyrocaine, resorcinol, risocaine, rodocaine, ropivacaine, tetracaine, troclocan, and pharmaceutically acceptable derivatives thereof, and combinations thereof.

20. (Original) The composition of claim 19 wherein the local anesthetic agent is selected from the group consisting of bupivacaine, chloroprocaine, dibucaine, etidocaine, levobupivacaine, lidocaine, mepivacaine, prilocaine, ropivacaine, tetracaine, and pharmaceutically acceptable derivatives thereof.

21. (Original) The composition of claim 1 which further comprises at least one irritation-mitigating additive.

22-42. (Canceled)

43. (Currently amended) A composition for the enhanced delivery of a local anesthetic agent through a body surface, comprising a formulation of:

- (a) a therapeutically effective amount of the local anesthetic agent;
- (b) a pharmaceutically acceptable inorganic base in an amount effective to provide a pH within the range of about 8.0-13.0 at the body surface during administration of the local anesthetic agent and to enhance the flux of the local anesthetic agent through the body surface without causing damage thereto; and

(c) a pharmaceutically acceptable carrier suitable for topical or transdermal drug administration,

wherein the base is present in an amount that is the total of

(a) the amount required to neutralize the acidic species plus

(b) an amount equal to about 0.5-4.0 wt % of the composition,

and the local anesthetic agent is selected from the group consisting of benzocaine, benzyl benzoate, bupivacaine, calamine, chloroprocaine, chloroxylenol, cinchocaine, cocaine, dexivacaine, diamocaine, dibucaine, dyclonine, etidocaine, hexylcaine, ketamine, levobupivacaine, lidocaine, menthol, mepivacaine, oxethazaine, phenol, pramoxine, prilocaine, procaine, proparacaine, propoxycaine, pyrrocaine, resorcinol, risocaine, rodocaine, ropivacaine, tetracaine, troclosen, and pharmaceutically acceptable derivatives thereof, and combinations thereof, the inorganic base comprising an inorganic hydroxide present in an amount of about 0.75 to 2.0% of a topically applied formulation or a drug reservoir of a drug delivery system or patch.